

Remarks

Introduction

Claims 25-38 were pending. By way of this response, the specification has been amended, claims 25-37 have been amended, and claim 38 has been cancelled without prejudice. The specification has been amended to correct various inadvertent typographical errors. Support for the amendments to the specification and claims can be found in the application as originally filed (e.g., including page 23, line 20 to page 24, line 27, page 31, line 22 to page 32, line 20, and SEQ ID NOs: 28, 40, 42, 50, 52, 60, 66, 71, and 77), and care has been taken to avoid adding new matter. Accordingly, claims 25-37 are currently pending.

Double Patenting

Claims 25-26 and 32-33 have been rejected under the judicially created doctrine of obviousness type double patenting over claims 1 and 2 of U.S. Patent No. 5,919,665. The Office Action also indicates that claims 25-26 and 32-33 conflict with claims 25-26, 29, 34-35, and 38 of U.S. Application No. 10/271,012, and that claims 25-38 conflict with claims 25-38 of U.S. Application No. 10/729,122, and claims 25-38 of U.S. Application No. 10/729,527.

Applicant does not concede the correctness of the rejections. However, to advance the prosecution of the above-identified application, claims 25-37 have been amended as set forth above. To the extent the obviousness-type double

patenting rejection has not been overcome, applicant will consider filing a Terminal Disclaimer upon the indication of allowable subject matter. In addition, applicant submits that the present amendments to the claims provide a clear line of demarcation between the commonly owned applications.

In view of the above, applicant submits the double patenting rejections have been overcome and respectfully requests withdrawal of the rejections.

Claim Objections

Claims 25 and 34 have been objected because claim 28 recites "wherein the toxin is in solution".

As indicated above, claims 25-37 have been amended. Applicant submits that the present claims, that is claims 25-37, do not include the objected language, and are definite.

In view of the above, applicant submits the claim objections have been overcome and respectfully requests withdrawal of the objections.

Rejection Under 35 U.S.C. § 102

Claims 25-38 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Dolly et al. (U.S. Pat. No. 6,203,794) as evidenced by Ledoux (1994).

Applicant traverses the rejections as it relates to the present claims.

Applicant submits that Dolly does not specifically disclose, teach, or suggest the present invention. For example, Dolly does not specifically disclose, teach, or even suggest a soluble recombinant botulinum toxin comprising a non-toxin protein sequence and receptor binding domain amino acid sequence of a botulinum toxin, as recited in the present claims.

In contrast to the present claims, Dolly discloses a recombinantly produced botulinum toxin type A light chain coupled to a native botulinum toxin type A heavy chain (i.e., a botulinum toxin heavy chain obtained from anaerobic Clostridium botulinum bacteria) and a recombinantly produced botulinum toxin type A light chain coupled to a maltose binding protein (e.g., see examples 11-22). In other words, Dolly discloses completely different and distinct proteins compared to the presently claimed toxins. As understood by persons of ordinary skill in the art, the botulinum toxin type A light chain is separate and distinct from the botulinum toxin receptor binding domain. For example, the botulinum toxin type A light chain and the botulinum toxin receptor binding domain have different amino acid sequences and different functions. In addition, based on the disclosure of Dolly, a person of ordinary skill in the art would conclude that the hybrid protein of a recombinant light chain and a native heavy chain does not include a non-toxin protein sequence, as recited in the present claims.

Since Dolly does not specifically disclose each and every element recited in the present claims, applicant submits that Dolly does not anticipate the present claims under 35 U.S.C. § 102.

In addition, applicant submits that the present claims are unobvious from and patentable over Dolly under 35 U.S.C. § 103 since Dolly specifically discloses botulinum toxin type A-based molecules having a recombinant botulinum toxin light chain coupled to a native botulinum toxin heavy chain and a recombinant botulinum toxin light chain coupled to a maltose binding protein. As discussed herein, Dolly provides no specific suggestion or motivation to a person of ordinary skill in the art to modify the teachings of Dolly to obtain a soluble recombinant botulinum toxin that comprises a non-toxin protein sequence and a receptor binding domain amino acid sequence of a botulinum toxin, as recited in the present claims.

In view of the above, applicant submits that the present claims, that is claims 25-37, are not anticipated by, and are unobvious from and patentable over, Dolly under 35 U.S.C. §§ 102 and 103.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present toxins including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.


Conclusion

In conclusion, applicant has shown that the present claims are not subject to double patenting, are in proper form, and are

not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims are allowable, and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below before mailing another Office Action.

Date: 6/10/05

Respectfully submitted,



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